WHITE PETROLATUM- petrolatum jelly Sion Biotext Medical Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Petrolatum Jelly

Active Ingredient

White Petrolatum (USP, 100% w/w)

Purpose

Skin Protectant

Uses:

- Helps treat and prevent diaper rash
- Helps seal out wetness
- Temporarily protects minor * cuts * scrapes * burns
- Temporarily helps protect and relieve chapped and cracked skin or lips
- Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash
- With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.

Warnings:

For external use only.

When using this product

• do not get into eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days.

Do not use on

- deep puncture wounds
- animal bites
- serious burns.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Change wet and soiled diapers promptly.
- Cleanse the diaper area and allow to dry.
- Apply as needed.

Other Information

- Store at 59-86°F (15-30°C)
- Avoid excessive heat

Principal Display Panel

WHITE PETROLATUM (USP) SKIN PROTECTANT

Drug Facts

Active ingredient White Petrolatum USP (100% w/w)....

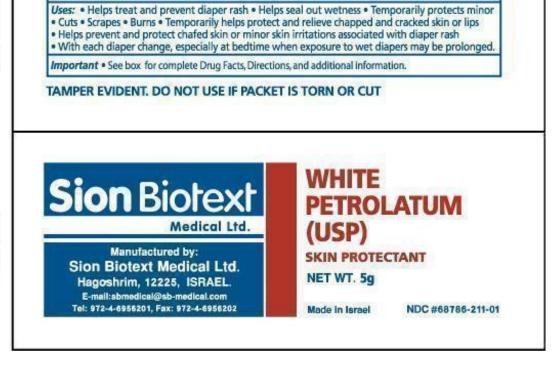
Made in Israel

88mm

Purpose Skin Protectant

36mm

36mm



Drug Facts

Active Ingredient Purpose White Petrolatum (USP, 100% w/w).....Skin Protectant

Uses: • Helps treat and prevent diaper rash • Helps seal out wetness • Temporarily protects minor • cuts

- scrapes burns Temporarily helps protect and relieve chapped and cracked skin or lips • Helps prevent and protect chafed skin or minor skin irritations associated with diaper rash
- With each diaper change, especially at bedtime when exposure to wet diapers may be prolonged.

Warnings: For external use only.

When using this product . do not get into eyes.

Drug Facts (continued)

Stop use and ask a doctor if • condition worsens • symptoms last more than 7 days or clear up and occur again in a few days.

Do not use on • deep puncture wounds
 • animal bites • serious burns.

Keep out of reach of children.

If swallowed, get medical help or contact
a Poison Control Center right away.

Directions: • Change wet and soiled diapers promptly.

- Cleanse the diaper area and allow to dry.
- Apply as needed.

Other information:

- Store at 59'- 86'F (15'-30'C)
- Avoid excessive heat.

Sion Biotext

Manufactured by:
Sion Biotext Medical Ltd.
Hagoshrim, 12225, ISRAEL.
E-mail:sbmedical@sb-medical.com

Tel: 972-4-6956201, Fax: 972-4-6956202

3

WHITE PETROLATUM (USP)

3*6

SKIN PROTECTANT NET WT. 1oz (28.35g)

-5

Made in Israel

NDC #68786-211-02

WHITE PETROLATUM

petrolatum jelly

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68786-211

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthPETROLATUM (UNII: 4T6 H12BN9 U) (PETROLATUM - UNII:4T6 H12BN9 U)PETROLATUM1 g in 1 g

Packaging Item Code **Package Description** Marketing Start Date | Marketing End Date 1 NDC:68786-211-01 6 in 1 CASE 02/16/2014 1 144 in 1 BOX 1 5 g in 1 PACKET; Type 0: Not a Combination Product 2 NDC:68786-211-02 72 in 1 CASE 02/16/2014 2 1 in 1 BOX 2 28.35 g in 1 TUBE; Type 0: Not a Combination Product NDC:68786-211-03 100 in 1 CASE 02/16/2014 3 28.35 g in 1 TUBE; Type 0: Not a Combination Product 4 NDC:68786-211-04 72 in 1 CASE 02/16/2014 4 1 in 1 BOX 4 56.7 g in 1 TUBE; Type 0: Not a Combination Product

5	NDC:68786-211-05	72 in 1 CASE	02/16/2014	
5		1 in 1 BOX		
5		92 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:68786-211-06	100 in 1 CASE	02/16/2014	
6		92 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:68786-211-07	6 in 1 CASE	02/16/2014	
7		12 in 1 BOX		
7		113 g in 1 TUBE; Type 0: Not a Combination Product		
8	NDC:68786-211-08	100 in 1 CASE	02/16/2014	
8		113 g in 1 TUBE; Type 0: Not a Combination Product		
9	NDC:68786-211-09	12 in 1 CASE	02/16/2014	
9		425 g in 1 JAR; Type 0: Not a Combination Product		
10	NDC:68786-211-10	24 in 1 CASE	02/16/2014	
10		284 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph final	part347	02/16/2014						

Labeler - Sion Biotext Medical Ltd (532775194)

Registrant - Sion Biotext Medical Ltd (532775194)

Establishment									
Name	Address	ID/FEI	Business Operations						
Sion Biotext Medical Ltd		532775194	manufacture (68786-211)						

Revised: 11/2020 Sion Biotext Medical Ltd